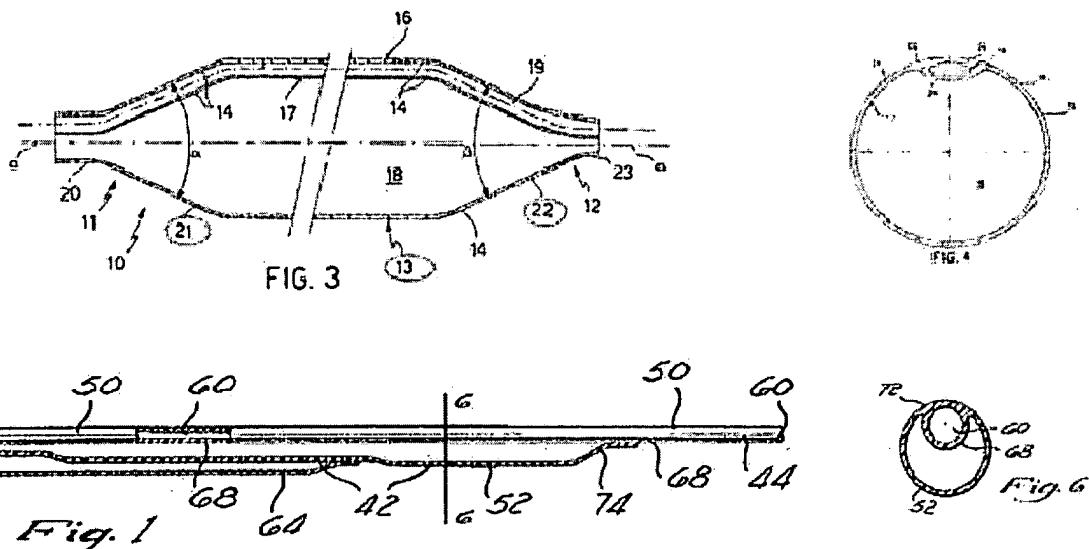


Remarks/Arguments:

This is a reply to the office action of July 7.

Claims 72, 101 and 105 have been amended. Support for these amendments are found in the description at paragraphs 0051, 0059, 0061 and 0062, and in Figures 1, 3, 9, 15, 16, 18, 19, 20, 22, and 23.

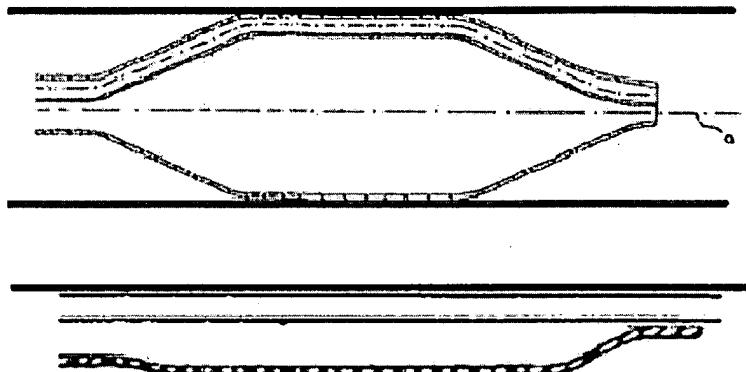


Comparing (see above) Figures 3, 4 of the present application with Figures 1 and 6 of Jang US '634, one can see that Jang does not disclose a cavity wall that follows the outline of the balloon structure, in particular the proximal and distal shanks; rather, Jang discloses a cavity that remains straight from the proximal portion to the distal portion of the balloon.

Jang does not disclose a cavity wall following the outline of the proximal shank.

Because the balloon structure includes a proximal shank, a distal shank and an intermediate portion between said proximal and distal shanks, where the balloon structure with the proximal and distal shanks, when the inflation chamber is expanded, has an outer surface of circular cross-section transverse the longitudinal extent of the balloon structure, in order to

deploy the balloon in all the radial directions, the proposed structure could be used in devices that should be symmetric and uniform.



Jang '634

A catheter having a shaped wall cavity that follows the shanks or an *axial-symmetric deployed balloon structure* is easy to maneuver and guide in the tortuous body vessels. This balloon, when inflated, automatically lie on the center line, the axis of the vessel, in other words this balloon is "self-centering".

A catheter having a uniform inflated/deployed shape all around – in all the radial directions – displaces or shifts the body vessel plaque uniformly, with the same pressure distributed in the entire treated lesion area.

The Jang solution is an asymmetric balloon deployed on one side of the catheter body, and therefore presents a preferred bending plane or a preferred bend direction. The asymmetric steering behavior of the Jang solution, give to the operator great difficulties in the phases of advancing the Jang catheter inside the body vessels.

The Jang balloon does not deploy the balloon in uniformly all the radial directions. The Jang balloon is not centered on the body longitudinal axis, but develops mainly in one radial direction (towards the bottom in the above figure). The Jang balloon, when inflated, acts in

a non-uniform way on the vessel walls: therefore a portion of the vessel wall should lacerate under the balloon asymmetric action due to the excessive expansion, while on the opposite vessel wall portion the lesion (the stenosis) should remain untreated, the vessel wall portion in contact with the catheter shaft (reference 50).

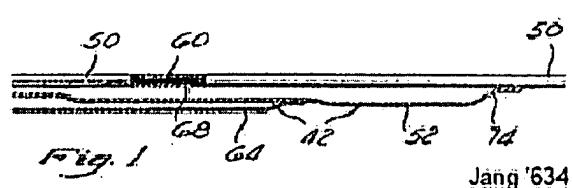
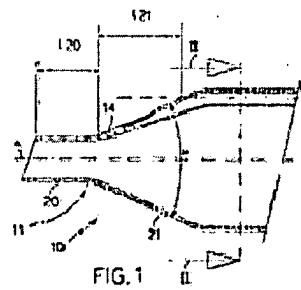
Due to:

- a balloon structure comprising a proximal shank, a distal shank and an intermediate portion between said proximal and distal shanks;
- a balloon structure with the proximal and distal shanks with an outer surface of circular cross-section transverse the longitudinal extent of the balloon structure, capable of deploying the balloon in all the radial directions; and
- a wall cavity that follows the balloon structure outline from the proximal shank to the distal shank;

it is possible to have the following advantages:

- a catheter completely symmetric and easy to maneuver inside the tortuous body vessels, facilitating the trackability to reach the interventional area of the lesion;
- a balloon with a symmetric structure and a wall cavity that follow the balloon wall from the proximal shank portion to the distal shank portion is effective and at the same time with an atraumatic contour;
- a symmetric balloon simplify the deflating operations of the balloon (facilitating the re-folding) and consequently the extraction of the catheter from the body vessel, as the balloon presents a homogeneous contour when folded.

Regarding claim 113, please note that the proximal port or aperture (see the marked areas of the following figures) that connects the wall cavity to the outside is completely missing in the Jang solution.



The Examiner determined that this feature is disclosed by Jang at Figure 1 reference 60. Please note, however, that the reference 60 in Figure 1 of Jang discloses a guide wire lumen, *not* an aperture, as clearly shown and as described at col. 11 line 33.

We believe the claims now presented distinguish the invention from the prior art of record, and that this application is in condition for allowance.

Respectfully submitted,

/Charles Fallow/

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